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EXAMINER	
YU, MELANIE J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/030,972	ABEL ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63 and 81-92* is/are pending in the application.

4a) Of the above claim(s) *48-63 and 92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47 and 81-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 March 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments and amendments filed 27 March 2009 has been entered.

Status of the Claims

2. Claims 1-63 and 81-92 are currently pending in the application. Claims 48-63 and 92 have been withdrawn. Claims 1-47 and 81-91 are examined on the merits.

Withdrawn Rejections

3. Applicant's amendments to the claims and specification overcome the previous rejection under 35 USC 112, first paragraph and the specification and claim objections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-34, 38-40, 42-47, 81-84 and 86-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. (WO 96/35940) in view of Coassin et al. (US 6,660,233).

Neuschäfer et al. teach a device comprising:

a sensor platform having one planar optical waveguide (pg. 13, last paragraph-pg. 14, line 4; pg. 5, paragraphs 3 and 4; a single optical waveguiding layer is applied to the substrate, pg. 8, paragraph 3 and parts a, b and c);

a sealing layer forming a tight seal with a sealing medium with the planar optical waveguide (a cover is part of a sealing layer that is glued to the sensor platform to form a unit, pg. 29, lines 1-17; pg. 13, last paragraph-pg. 14, line 5);

a plurality of recesses opening at least towards the sensor platform (a cover which is part of the sealing layer has recesses, central cut out portions, comprising inlet and outlet openings for solutions, pg. 14, lines 6-12), each of the recesses forming a corresponding sample compartment in a 2-dimensional arrangement wherein at least two sample compartments are in a length direction of the array and at least two sample compartments are in a width direction of the array (central cut out portions form a flowthrough cell, which is the sample compartment, the sample compartments are formed in a 2-dimensional arrangement, pg. 14, lines 6-12, 7, Fig. 5a and 5b), wherein

each of the sample compartments comprise different biological recognition elements, for specific recognition and binding of different analyte (pg. 14, lines 11-12; pg. 21, lines 19-24; immobilized recognition elements that are specific to different analyte indicates that the recognition elements are different, pg. 13, lines 11-16; pg. 8, lines 22-24; pg. 18, lines 3-6; pg. 34, line 26-pg. 25, line 5; pg. 45, lines 3-5) and are immobilized in 5 to 50 discrete measurement areas, which encompasses the recited five or more, in a two-dimensional array on the planar optical waveguide (number of

individual waveguiding regions, pg. 13, lines 7-8; recognition elements immobilized on waveguiding regions, pg. 14, lines 11-12; detection regions, pg. 13, lines 21-22),

the measurement areas are in optical interaction with an excitation light emanating from the optical waveguide as part of the sensor platform which forms a demarcation of the sample compartments (pg. 7, lines 18-19; pg. 8, lines 22-24; pg. 17, lines 5-6), and

the sample compartments are operable such that samples received therein are removable therefrom and further sample solutions are receivable therein (outlet indicates that samples are removable and further samples are receivable, pg. 14, lines 8-10). Although Neuschäfer et al. teach the waveguiding layer separated into at least two waveguiding regions, the entire waveguiding layer that is layered on the substrate is considered a single waveguiding layer (pg. 8, paragraph 3 and parts a, b and c) and therefore the sensor platform has one planar optical waveguide with discrete measurement areas arranged on the waveguide.

Neuschäfer et al. fail to teach the measurement areas being arranged in an array wherein there are at least two measurement areas in a width direction of the array and at least two measurement areas in a length direction of the array.

Coassin et al. teach an array on a waveguide (col. 1, lines 60-65) having an array of measurement areas wherein the array has a linear arrangement of immobilized biological reactants (col. 2, lines 40-44) or has at least two measurement areas in a width direction and at least two measurement areas in a length direction (col. 2, lines

44-48), in order to provide distinct regions of active sites for detection of target biomolecules.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Neuschäfer et al., an arrangement having at least two measurement areas in a width direction of an array and two measurement areas in a length direction of an array as taught by Coassin et al. It would have been obvious because Coassin et al. teach that either a linear arrangement of measurement areas or a two-dimensional array arrangement with at least two measurement areas in both a length and width direction are well known in the art to produce rapid and equivalent detection results of a target biomolecule, and therefore either array arrangement of measurement areas can be used for detection of target biomolecules. Furthermore, rearranging the measurement areas from a linear array to an array with more than one measurement area in the length and width directions would have been obvious because it has been held that rearranging parts of an invention involves only routine skill in the art. See *In re Japikse,* 86 USPQ 70.

Regarding claims 2 and 3, Neuschäfer et al. teach one measurement area in each of the sample compartments used for referencing (quality control, pg. 36, lines 23-24). Neuschäfer et al. also teach the referencing measurement areas reference same chemical parameters in a number of sample compartments distributed over the sensor platform (same control molecules, used for referencing, are immobilized in strips on five regions, pg. 36, lines 25-26). Neuschäfer et al. do not specifically teach lateral distribution of the chemical parameters over the sensor platform. However, such a

limitation is drawn to intended use of referencing measurement areas and do not require any further product limitations. Therefore, since the device of Neuschäfer et al. comprise the limitations recited in claims 1 and 2, the device of Neuschäfer et al. would be capable of providing such determination of chemical parameters.

With respect to claim 4, Neuschäfer et al. teach measurement areas in optical interaction with an evanescent field of the excitation light guided in the planar optical waveguide (pg. 6, last line-pg. 7, line 3).

Regarding claims 5 and 6, Neuschäfer et al. teach the planar optical waveguide being self-supporting (pg. 5, lines 24-29) and part of the sensor platform being a multi-mode or single-mode waveguide comprising glass (pg. 15, line 10), which is optically transparent at the excitation wavelength (pg. 15, lines 13-14).

With respect to claims 7-13, Neuschäfer et al. teach the planar optical film waveguide comprising a first optically transparent layer, a waveguiding layer, on a second optically transparent layer, made of glass, wherein the second optically transparent layer has a lower refractive index than the first layer (pg. 10, lines 12-17; pg. 15, lines 19-22) and wherein the refractive index of the first optically transparent layer is higher than 2.0 (pg. 16, lines 2-3), which encompasses the recited greater than 1.8, and is made of TiO_2 (pg. 15, lines 4-5). Neuschäfer et al. also teach the thickness of the first optically transparent layer between 40 and 1000 nm (pg. 15, lines 7-8), which encompasses the recited between 40 and 300 nm. Neuschäfer et al. also teach an additional optically transparent layer located between the first and second optically transparent layers, and in contact with the first optically transparent layer (substrate is

covered with thin layer, which indicates contact, pg. 15, lines 18-20), and having a thickness of less than 10,000 nm (pg. 15, lines 17-18), which encompasses the recited range of 5-10,000 nm, wherein the purpose of the additional layer is to reduce the surface roughness below the first optically transparent layer (pg. 15, lines 18-22).

Regarding claims 14-16, Neuschäfer et al. teach an the device further comprising an adhesion-promoting layer deposited on the first optically transparent layer for the immobilizing biological recognition elements (pg. 19, lines 14-16), having a thickness of less than 50 nm (pg. 19, lines 17-18), which is encompassed by the recited less than 200 nm, and a comprising chemical compounds of silanes (pg. 12, lines 15-20).

With respect to claims 17-18 and 81, Neuschäfer et al. teach measurement areas generated by deposition of biological elements on the sensor platform (Fig. 3-5; pg. 13, last paragraph-pg. 14, line 2; pg. 18, lines 12-13). Although Neuschäfer et al. do not specifically teach the areas generated by deposition of biological recognition elements, such a limitation does not appear to physically further limit the product recited in claims 1 and 17. It is unclear what product limitations are set forth by areas generated by laterally selective deposition, and since the same product limitations are taught by Neuschäfer et al. as recited in claims 1 and 17, the product of Neuschäfer et al. would be capable of comprising measurement areas generated by deposition of biological elements. Neuschäfer et al. teach a method of deposition comprising ink jet spotting (pg. 18, lines 15-21).

Regarding claims 19 and 20, Neuschäfer et al. teach a biological recognition element being nucleic acids (pg. 21, lines 19-24), including DNA which comes from a cell and is considered a cell fragment.

With respect to claims 21-22, Neuschäfer et al. teach “chemically neutral” compounds such as bovine serum albumin, to minimize nonspecific binding (pg. 37, lines 23-29; pg. 40, lines).

Regarding claims 23-26, Neuschäfer et al. teach the first optically transparent layer having at least one grating structure formed therein for incoupling excitation light to the measurement areas (pg. 16, lines 22-25), and the first optically transparent layer having at least one grating structure formed therein for outcoupling of light into the first optically transparent layer (pg. 17, lines 5-13). Neuschäfer et al. also teach the incoupling and out coupling grating structures interchangeable with respect to incoupling and outcoupling (pg. 17, lines 6-7).

With respect to claims 27-29, Neuschäfer et al. teach grating structures having a period of 200 nm – 1000 nm and a grating modulation depth of 3-100 nm (pg. 16, last paragraph), wherein the ration of the grating modulation dept to thickness of the first optically transparent layer is equal to or smaller than 0.2 (pg. 16, lines 11-12). Neuschäfer et al. further teach grating structures being rectangular with a periodic modulation of the refractive index in the planar optically transparent layer (rectangular, pg. 16, lines 16-17).

Regarding claim 30, Neuschäfer et al. teach a thin metal layer, gold, deposited between the first optically transparent layer and the immobilized biological recognition

elements, wherein the thickness of the metal can be excited at a luminescence wavelength (pg. 11, lines 11-15).

With respect to claims 31-34, Neuschäfer et al. teach a grating structure having a diffractive grating with a uniform period (pg. 16, last paragraph) or a multi-diffractive grating (1-3 modes is a multi-diffractive grating, pg. 18, lines 1-2). Neuschäfer et al. further teach the incoupling and outcoupling grating structures located outside a region of the sample compartments (grating located in and out of sample compartment, 3,3', Fig. 6; pg. 9, lines 23-24) and grating structures extend over at least a portion of the sample compartments (one periodicity indicates one grating structure over all sample compartments; pg. 16, last paragraph).

Regarding claims 38, 39, 82 and 83, Neuschäfer et al. teach a sealing material, comprising polysiloxane (pg. 12, lines 15-20), and is self-adhesive (pg. 34, lines 4-7).

With respect to claims 40, 42, 84 and 86, Neuschäfer et al. teach 2-100 measurement areas in one sample compartment (pg. 13, lines 22-23), which is encompassed by the recited 2-1000 measurement areas. Neuschäfer et al. also teach the sample compartments having a volume of 0.07 ml (pg. 34, line 5), which is encompassed by the recited 100 nl-1ml.

Regarding claims 43 and 87, Neuschäfer et al. the device comprising sample compartments closed at a side facing away from the sensor platform except for inlet and outlet openings for sully and removal of samples (Fig. 5b; pg. 14, lines 6-12). Neuschäfer et al. fail to teach supply or removal of samples performed in a closed flow-through system, wherein common inlet and outlet openings are addressed row by row

or column by column. However, such limitations do not appear to further limit the product limitations recited in claims 1, 43 and 87. Therefore, since Neuschäfer et al. teach the product limitations recited in claims 1, 43 and 87, the device of Neuschäfer et al. would be capable of performing such supply or removal of samples.

With respect to claims 44 and 88, Neuschäfer et al. fail to teach supply of samples affected by pressure differences or electric potentials. However, such a limitation does not appear to provide further product limitations to the product of claims 1 and 44. Therefore since Neuschäfer et al. teach the recited product limitations of claims 1 and 44, the device of Neuschäfer et al. would be capable of affecting the sample supply with the recited pressure differences or electric potentials.

Regarding claims 45-47 and 89-91, Neuschäfer et al. teach sample compartments having openings for locally addressed supply or removal of samples or other reagents at the side facing away from the sensor platform (inlet and outlet openings for solutions, pg. 14, lines 6-12). Neuschäfer et al. further teach compartments provided for reagents (reagents are contained in a compartment when introduced into the flow-through device, pg. 36, lines 8-10). Neuschäfer et al. also teach mechanically recognizable marks are provided on the sensor platform, in order to facilitate the adjustment in an optical system (depression cut for waveguide so waveguiding layer faces the cannels and facilitates optical detection, pg. 37, lines 7-13).

2. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. in view of Coassin et al., as applied to claim 1, further in view of Hashimoto et al. (US 6,480,639).

Neuschäfer et al. in view of Coassin et al., as applied to claim 23, teach a device comprising a tight sealing layer, but fail to teach the material being optically transparent or optically absorbent.

Hashimoto et al. teach a sealing layer being optically transparent or absorbent (col. 16, lines 54-63), in order to block leakage lights from the light emitting device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Neuschäfer et al. in view of Coassin et al., an absorbent or transparent sealing layer as taught by Hashimoto et al., in order to more effectively seal the optical device and fix optical fibers.

Hashimoto et al. also teach a 2 layer system wherein a first layer that is transparent to excitation radiation is brought into contact with a sensor platform (col. 16, line 54-57), and a second layer absorbent in a spectral range of the excitation radiation is present and located remotely from the sensor platform (col. 16, lines 58-63).

3. Claims 41 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. (WO 96/35940) in view of Coassin et al. (US 6,660,233).

Neuschäfer et al. in view of Coassin et al., as applied to claim 1, teach a device comprising a sample compartment occupying an area of 9 mm^2 (pg. 36, last 2 lines). Neuschäfer et al. fail to teach an area of 0.001-6 mm^2. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d

454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 41 and 85 are for any particular purpose or solve any stated problem, and the prior art teaches that the measurement area can be varied in order to accommodate different sample volumes, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the flow-through device art.

Response to Arguments

4. Applicant's arguments filed 27 March 2009 have been fully considered but they are not persuasive.

At pages 19-20 applicant argues that Neuschäfer explicitly describe the use of several measurement areas on a continuous waveguiding layer as being disadvantageous and one having ordinary skill in the art would not believe that arranging specific binding partners in a single wave guide layer would result in a device with high sensitivity. Applicant further argues that Neuschäfer et al. teaches that various specific binding partners applied to a single waveguiding layer will have a low degree of selectivity.

Applicant's argument is not persuasive because the claim recites a sensor platform having <u>one</u> planar optical waveguide, and does not require that this planar

optical waveguide must be continuous. Therefore the waveguiding layer taught by Neuschäfer et al. at page 8, paragraph 3, parts a, b and c, is a single waveguide layer on a sensor platform. Although this waveguide has several measurement areas and describes the waveguiding layer being split into separate waveguiding regions, the waveguide is a single waveguiding layer and therefore the sensor platform taught by Neuschäfer et al. has a single waveguide with discrete measurement regions.

At page 20 applicant states that Neuschäfer et al. describe a measurement cell comprising at least two discrete waveguiding regions wherein one measurement area is identical with one of the planar waveguiding regions. Applicant further states that a combination with Coassin et al. would lead to a two-dimensional arrangement of planar wave-guiding regions of each of the measurement areas discrete from each other within a measurement cell. Applicant argues that a combination would not have the miniaturization potential as well as the reduced production costs of reached by the present invention.

Applicant's argument is not persuasive because such limitations are not recited in the rejected claims and do not provide any structural limitations to the device. The combination of Neuschäfer in view of Coassin teach the required structural limitations and therefore read on the limitations recited in the claims.

At pages 20-21 applicant argues that Coassin et al. is drawn to a linear array and 2-dimensional array structure in a spotting arrangement, but would not be equivalent in planar waveguide technology because light entering a planar waveguide has to be strictly oriented in a direction x perpendicular to a direction y in order to achieve optimal

resonance conditions. Applicant argues that the linear array and 2-dimensional array are therefore not optically equivalent.

Applicant's argument is not persuasive because given the functional equivalence of the linear and 2-dimensional arrangements of measurement areas taught by Coassin and the separate waveguiding regions taught by Neuschäfer et al., one having ordinary skill would have recognized that light in each measurement area can be controlled separately. Therefore rearranging the measurement areas into 2-dimensional arrangements of measurement areas instead of linear as taught by Coassin would have required routine skill in the art of rearranging the measurement areas and would not have required different waveguide measurement techniques.

At page 21 applicant argues that Neuschäfer teaches a linear array in the "y direction" wherein one measurement cell comprises a linear array of discrete measurement areas with discrete waveguiding regions parallel to each other and Henron teaches a linear array wherein one measurement cell is made of one waveguiding regions comprising a linear array of measurement areas in the direction of propagation of the excitation light "x" and the state of the art thus confirms the non-equivalency of directions x and y in optical waveguides and that rearrangements from a linear array to a 2-dimensional array would not require only routine skill in the art.

Applicant's argument is not persuasive because although Henron teaches a linear array in a different waveguiding direction than Neuschäfer, such an argument is not relevant because each measurement area of Neuschäfer has a separate waveguiding region on the single planar optical waveguide. Therefore the

rearrangement of waveguiding regions on the single optical waveguide layer of Neuschäfer does not require more than routine skill in the art and is merely a rearrangement of structural features. The combination of Neuschäfer and Coassin does not require a change in optical waveguide detection because each waveguiding region is detected separately. Furthermore, the reference of Henron exhibits that the detection resulting from rearrangement of an array to a different orientation on a single optical waveguide is well known and requires only routine skill in the art.

Conclusion

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641